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| 10/748,589 | 12/30/2003 | Thomas L.C. Simpson | EIS-5909H (1417G P 984) | 8944 |
| 29200 | 7590 | 05/28/2009 | EXAMINER | |
| BAXTER HEALTHCARE CORPORATION 1 BAXTER PARKWAY DF2-2E DEERFIELD, IL 60015 | | RAPILLO, KRISTINE K | | |
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| | | | 3626 | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/748,589 | SIMPSON ET AL. | |
| | Examiner | Art Unit | |
| | KRISTINE K. RAPILLO | 3626 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 25 February 2009.
 2a) This action is **FINAL**. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-32 is/are pending in the application.
 4a) Of the above claim(s) 2, 21 - 23, 27 and 29 is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 1,3-20,24-26,28 and 30-32 is/are rejected.
 7) Claim(s) 26 is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on 07 November 2008 is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|----------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ . |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>8/6/2004; 7/6/2005</u> . | 6) <input type="checkbox"/> Other: _____ . |

DETAILED ACTION

Notice to Applicant

1. This communication is in response to the amendment submitted February 25, 2009. Claims 1, 11, 13 - 16, and 24 - 26 are amended. Claims 21 – 23, 27, and 29 are cancelled (claims 2 and 29 were previously cancelled). Claims 31 and 32 are new. Claims 1, 3 – 20, 24 – 26, 28, and 30 - 32 are presented for examination.

Claim Objections

2. Claim 26 is objected to because of the following informalities: Claim 26 is directed to neither a “process” nor a “machine,” but rather embraces or overlaps two different statutory classes of invention. For example, claim 26, which is dependent on method claim 1, contains the following indefinite language: “The system of claim 26”. Appropriate correction is required.

Claim Rejections - 35 USC § 102

3. The 35 U.S.C. 102 (e) rejections of claims 1, 3 – 6, 9, 10, and 26 are hereby withdrawn based upon the amendment submitted February 25, 2009.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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5. Claims 1, 3—6, 9 – 12, 14—16, 24 – 26, 28, and 30 - 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reuss et al., herein after Reuss (U.S. Patent Number 6,364,834) in view of Lebel et al., herein after Lebel (U.S. Publication Number 2002/0016568 A1).

In regard to claim 1 (Currently Amended), Reuss teaches a method for executing a notification process within a healthcare system comprising the steps of:

transmitting the signal relating to the notification condition to a first clinician's device (column 5, lines 13 – 64) where Reuss discloses bidirectional communication such that the first caregiver can receive an alarm notification regarding a patient;

indicating the notification condition on the clinician's device (column 5, lines 30 – 37; column 4, line 55 through column 5, line 12; and, column 15, lines 48 - 60) where the message may include patient identification, patient location, and alert information;

operating a timer to determine if a response to the notification condition is received during a predefined timer limit (column 5, lines 38 – 64) where a pre-selected time period indicates the use of a timer; and,

if the response to the notification condition is not received prior to the predefined timer limit, transmitting the signal relating to the notification condition to a second clinician's device (column 5, lines 38 – 64 and column 9, line 56 through column 10, line 5) where Reuss discloses a method in which a message/notification is sent to a second clinician (or caregiver) within a pre-selected time period.

Lebel teaches a method comprising the steps of: generating a signal at an infusion pump that a notification condition related to an administration of a medication to a patient by the infusion pump exists for the specific patient (paragraphs [0021], [0038], [0159], and [0182]; claims 1 and 21) where Lebel discloses emitting a notification signal to or from an infusion pump if an alarm condition exists; and if the response to notification is received prior to the predefined timer limit, not transmitting the signal relating to the notification condition to the second clinician's device (paragraph [0099]) where the alarm is reasserted if the alarm has not been cleared within a predefined period of time.

Therefore, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to include a method comprising the steps of: generating a signal at an infusion pump that a notification condition related to an administration of a medication to a patient by the infusion pump exists for the specific patient and if the response to notification is received prior to the predefined timer limit, not transmitting the signal relating to the notification condition to the second clinician's device as taught by Lebel, within the method of Reuss, with the motivation of providing an infusion pump (i.e. medical device) which can detect and report alarm conditions in regard to the delivery of medication (paragraph [0198], including table).

In regard to claim 3 (Original), Reuss and Lebel teach a method as per claim 1. Reuss teaches a method further comprising the step of transmitting the signal relating to the notification condition to a charge clinician (column 4, line 55 through column 5, line 12 and column 15, lines 48 - 60).

In regard to claim 4 (Previously Presented), Reuss and Lebel teach a method as per claim 1. Reuss teaches a method wherein the step of transmitting the signal to the second clinician's device is executed when the timer elapses (column 5, lines 38 – 64 and column 9, line 56 through column 10, line 5).

In regard to claim 5 (Original), Reuss and Lebel teach a method as per claim 1. Reuss teaches a method wherein the step of transmitting the signal relating to the notification condition to the first clinician's device comprises transmitting a wireless notification condition signal to the first clinician's device (column 3, lines 35 – 39; column 3, lines 45 – 50; column 4, lines 1 – 4; and, column 4, lines 22 - 54).

In regard to claim 6 (Original), Reuss and Lebel teach a method as per claim 1. Reuss teaches a method wherein the step of transmitting the signal relating to the notification condition to the second

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clinician's device comprises transmitting a wireless notification condition signal to the second clinician's device (Column 5, lines 25 – 30 and column 5, lines 56 – 64).

In regard to claim 8 (Original), Reuss and Lebel teach a method as per claim 1. Reuss teaches a method wherein there is a many-to-many relationship between first clinicians and charge clinicians (column 5, lines 25 – 37) where a first clinician and charge clinician are equated to primary physicians, specialists, and other forms of caregivers.

In regard to claim 9 (Original), Reuss and Lebel teach a method as per claim 1. Reuss teaches a method wherein the step of transmitting the signal comprises sending the signal to one of a PDA, a mobile phone, a pager, an e-mail address, an instant messaging receiver or a conventional telephone (column 15, line 48 through column 16, line 14).

In regard to claim 10 (Original), Reuss and Lebel teach a method as per claim 1. Reuss teaches a method wherein the step of transmitting the signal to the first clinician's device comprises sending the signal simultaneously to at least two of a mobile phone, a pager, an e-mail address, an instant messaging receiver or a conventional telephone (column 15, line 48 through column 16, line 14).

In regard to claim 11 (Currently Amended), Reuss teaches a system for providing messages to remote clinician devices in a healthcare system comprising:

a first central computer attached to a network (Figures 1 and 2; column 3, line 63 through column 4, line 4; column 4, lines 22 – 41; and column 10, lines 43 – 48) where Reuss discloses a central monitoring system which is equated to a central computer linked to a network;

a remote device associated with the clinician and operably attached to the network, the remote device comprising a visual display (column 3, line 63 through column 4, line 64; column 5, lines 13 - 64; and, column 15, lines 28 - 40) where Reuss discloses a remote device (i.e. PDA) linked, via a network with a display module; and

a request generated by the remote device and received by the first central computer (column 15, lines 13 – 37) where Reuss discloses that a remote device may forward information to a central computer.

Lebel teaches a system comprising: a response message generated (paragraphs [0157], [0317], [0318], and [0332]) by the first central computer (paragraphs [0110] and [0115]; claims 6 and 15) and sent to the remote device through the network (paragraphs [0317], [0318], and [0332]; Lebel does not specifically disclose a network, however, this feature is taught by Reuss and is referenced above), the response message including information contained within a data packet generated by an infusion pump, wherein the information contained within the data packet includes at least one of status information related to an administration of a medication to a patient by the infusion pump (paragraphs [0136], [0207], and [0318]) and programming information for the infusion pump (paragraphs [0161], [0162], [0163], [0187], and [0188]) where feedback is equated to status; and, wherein the response message generated by the first central computer is provided in a humanly readable format on the visual display of the remote device (Figure 2 and paragraph [0138]) where the remote device includes an LCD panel to ensure a human readable format.

The motivation to combine the teachings of Lebel and Reuss is discussed in the rejection of claim 1, and incorporated herein.

In regard to claim 12 (Original), Reuss and Lebel teach a system as per claim 11. Reuss teaches a system further comprising: a second computer attached, via a communication link, to the first central computer at least partially located within a health care facility, wherein the request generated by the remote device is received by the first central computer and the second central computer, wherein a response message is generated by the second central computer in response to the request generated by the remote device, and wherein the response message generated by the first central computer comprises the response message provided by the second central computer and additional data added by the first central computer (column 17, lines 3 - 32).

In regard to claim 14 (Currently Amended), Reuss and Lebel teach a system as per claim 12.

Reuss teaches a system wherein the remote device receives a second response message generated by the second central computer in response to a second request generated by the remote device, wherein the second response message and the second request are routed through the first central computer (column 17, lines 3 – 32).

In regard to claim 15 (Currently Amended), Reuss teaches a system for providing messages to remote clinician devices in a healthcare system, comprising: a request message generated by a program within a software application executed by a clinician device attached to a network (column 4, line 55 through column 5, line 12 and column 15, lines 48 - 60).

Lebel teaches a system comprising: a response message (paragraphs [0157], [0317], [0318], and [0332]) generated by a first computer (paragraphs [0110] and [0115]; claims 6 and 15) attached to the network and sent to the clinician device through the network in response to the request message (paragraphs [0317], [0318], and [0332]; Lebel does not specifically disclose a network, however, this feature is taught by Reuss and is referenced above) and including information contained within a data packet generated by an infusion pump, wherein the information contained within the data packet includes at least one of status information related to an administration of a medication to a patient by the infusion pump (paragraphs [0136], [0207], and [0318]) and programming information for the infusion pump (paragraphs [0161], [0162], [0163], [0187], and [0188]).

The motivation to combine the teachings of Lebel and Reuss is discussed in the rejection of claim 1, and incorporated herein.

In regard to claim 16 (Currently Amended), Reuss and Lebel teach a system as per claim 15. Reuss teaches a system wherein the information is modified in response to a change in the information contained within another data packet generated by the infusion pump (column 5, lines 13 – 37; column 7,

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lines 15 – 58; column 11, lines 15 – 26; column 12, lines 25 – 50; column 14, lines 12 - 33; and, column 16, lines 2 - 15).

In regard to claim Claim 24 (Currently Amended), Reuss and Lebel teach the method of claim 1.

Lebel teaches a method wherein the notification includes at least one of status information (paragraphs [0136], [0207], and [0318]) and programming information for the infusion pump (paragraphs [0161], [0162], [0163], [0187], and [0188]).

The motivation to combine the teachings of Lebel and Reuss is discussed in the rejection of claim 1, and incorporated herein.

In regard to Claim 25 (Currently Amended), Reuss and Lebel teach the method of claim 1.

Lebel teaches a method further comprising the steps of (i) determining whether one of the infusion pump and the clinician's device provides a response to the notification condition prior to a predefined timer limit (paragraphs [0021], [0038], [0159], and [0182]), and (ii) executing an escalated notification process if the response is not received prior to the predefined timer limit (paragraph [0099]).

The motivation to combine the teachings of Lebel and Reuss is discussed in the rejection of claim 1, and incorporated herein.

In regard to Claim 26 (Currently Amended), Reuss and Lebel teach the system of claim 1.

Lebel teaches a system further comprising software installed on the first clinician's device having a time-out output, wherein the time-out output indicates a loss of a wireless communication link between the first clinician's device (paragraphs [0133], [0170], and [0306]) and the infusion pump where an alarm is generated in response to an anomaly (paragraphs [0099] and [0177]) where any event that is outside what would be considered normal, or expected, would be considered an anomaly, thus triggering the alarm.

The motivation to combine the teachings of Lebel and Reuss is discussed in the rejection of claim 1, and incorporated herein.

In regard to Claim 28 (Previously Presented), Reuss and Lebel teach the system of claim 11.

Lebel teaches a system wherein the response message includes a display icon configured to access a list of a plurality of notification conditions corresponding to a specific patient from the first central computer (paragraphs [0132], [0138], and [0199] and table).

The motivation to combine the teachings of Lebel and Reuss is discussed in the rejection of claim 1, and incorporated herein.

In regard to Claim 30 (Currently Amended), Reuss and Lebel teach the system of claim 15.

Lebel teaches a system wherein the software application is configured to provide access to a list of a plurality of active infusion pump alerts associated with a specific patient (paragraphs [0157], [0320], [0321], and [0323]).

The motivation to combine the teachings of Lebel and Reuss is discussed in the rejection of claim 1, and incorporated herein.

In regard to claim 31, Reuss and Lebel teach the system of claim 11. Reuss teaches wherein the first computer is a central hospital computer (column 6, lines 10 – 35).

In regard to claim 32, Reuss and Lebel teach the system of claim 12. Reuss teaches wherein the second computer is a pharmacy computer (column 6, lines 10 – 35).

6. Claims 7, 13, 17 – 18, and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reuss et al., herein after Reuss (U.S. Patent Number 6,364,834) in view of Lebel et al., herein after Lebel (U.S. Publication Number 2002/0016568 A1) and further in view of Dempsey et al., herein after Dempsey (U.S. Patent Number 6,057,758).

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In regard to claim 7 (Original), Reuss and Lebel teach a method of executing a notification process as per claim 1.

Dempsey teaches a method wherein there is a many-to many relationship between first clinicians and patients (column 8, lines 47 – 55).

Therefore, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to include a method wherein there is a many-to many relationship between first clinicians and patients as taught by Dempsey with the motivation of allowing a physician or other health care provider the means of remotely monitoring the health status of patients in their care (column 4, lines 40 – 54).

In regard to claim 13 (Currently Amended), Reuss and Lebel teach a system, including a remote device and response message generated by a central computer, as per claim 12.

Dempsey teaches a system wherein said remote device further includes a browser responsive to the response message generated by the first central computer (column 10, lines 36 – 45).

The motivation to combine the teachings of Dempsey, Lebel, and Reuss is discussed in the rejection of claim 7, and incorporated herein.

In regard to claim 17 (Original), Reuss and Lebel teach a system, as per claim 16.

Dempsey teaches a system wherein the program is written in JAVA (column 6, lines 35 - 48).

The motivation to combine the teachings of Dempsey, Lebel, and Reuss is discussed in the rejection of claim 7, and incorporated herein.

In regard to claim 18 (Original), Reuss and Lebel teach a method of executing a notification process as per claim 16.

Dempsey et al. teaches a system wherein the program is written in C# (column 10, lines 38 – 45). C# is also known as C-Sharp. Dempsey et al. discloses an object oriented programming language of which C-Sharp (or C#) is included.

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Therefore, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to include a system where the program is written in C# as taught by Dempsey et al. with the motivation of providing a software program which provides an interface with the handheld terminals such as a PDA (column 9, lines 31- 32).

In regard to claim 20 (Original), Reuss and Lebel teach a system, as per claim 15.

Dempsey teaches a system wherein the software application is a Web browser (column 10, lines 36 – 45).

The motivation to combine the teachings of Dempsey, Lebel, and Reuss is discussed in the rejection of claim 7, and incorporated herein.

7. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Reuss et al., herein after Reuss (U.S. Patent Number 6,364,834) in view of Lebel et al., herein after Lebel (U.S. Publication Number 2002/0016568 A1) as applied to claim 16 above, and further in view of www.catharsismedical.com (12/9/01).

In regard to claim 19 (Original), Reuss and Lebel teach the system of claim 16.

www.catharsismedical.com teaches a system wherein the program is written in Visual Basic Script (paragraph 6). www.catharsismedical.com uses Windows NT which is a Visual Basic Script.

Therefore, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to include a system wherein the program is written in Visual Basic Script as taught by www.catharsismedical.com with the motivation of allowing the infusion pump and hardware to send messages to a Windows NT server (paragraph 17).

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Response to Arguments

8. Applicant's arguments filed February 25, 2009 have been fully considered but they are not persuasive. Applicant's arguments will be addressed herein below in the order in which they appear in the response filed February 25, 2009.

The Examiner has applied new references to the amended claims. The Examiner notes that the amended limitations were not in the previously pending claims; as such, Applicant's remarks with the regard to the application of Reuss, Dempsey, Bar-Gadda, Eggers, Mault, and www.catharsismedical.com are moot.

Conclusion

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to KRISTINE K. RAPILLO whose telephone number is (571)270-3325. The examiner can normally be reached on Monday to Thursday 6:30 am to 4 pm Eastern Time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Luke Gilligan can be reached on 571-272-6770. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

KKR

/C. Luke Gilligan/
Supervisory Patent Examiner, Art Unit 3626